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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,839	03/30/2004	Theoharis C. Theoharides	51275/151	3048

28538 7590 06/17/2008

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EXAMINER	
HAGOPIAN, CASEY SHEA	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,839	THEOHARIDES, THEOHARIS C.	
	Examiner	Art Unit	
	Casey S. Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 12/26/2007.

Claims 39-44 are pending. Claims 39, 41 and 42 have been amended. It is noted that claims 43 and 44 have also been amended even though the status identifiers indicate "original". Claim 43 replaced "the composition of claim 40" with "the composition of claim 39" and claim 44 replaced "the composition of claim 43" with "the composition of claim 42". Applicant's Remarks at page 3 clearly indicate this amendment in order to correct the antecedent basis of the claim.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of prior-filed nonprovisional application No. 09/056,707 under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed nonprovisional application is improper. Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/771,669, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Specifically, application '669 does not have support for the limitations, "protecting pelvic tissues from the inflammatory components of endometriosis" and "hydroxyzine". According to the PTO's records, PCT/US02/00476 is a CON of application '669, thus the PCT also lacks support for the instant claimed invention.

Accordingly, applicants are not afforded priority to applications PCT/US02/00476, 09/771,669 and 09/056,707. Therefore, without evidence to the contrary, the filing date of 3/30/2004 is also deemed the priority date for the instant application.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 9/14/2007:

Claim Objections

Claim 39 is objected to because of the following informalities: a "." is missing at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**. There is no teaching of "protecting against the inflammatory components of pelvic endometriosis" ; the subject matter is not properly described as filed. The specification states, "[p]elvic inflammatory conditions, such as presents in endometriosis, can also be treated with the inventive compositions" (paragraph [034]) and as such it is suggested that applicant incorporate the same language drawn to "treating" or "treatment" in the claims. Applicant is invited to identify the portion of the specification that teaches said limitation,

as the examiner has not been able to locate the applicable disclosure. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection**. There is no teaching of the claimed ranges, "10-3,000 mg of chondroitin sulfate, quercetin, myricetin or rutin" and "25-100 mg of hydroxyzine"; the subject matter is not properly described as filed. Applicant is invited to identify the portion of the specification that teaches said limitation, as the examiner has not been able to locate the applicable disclosure. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsberg et al. (US 2006/0210551 A1).

Lindsberg teaches compositions comprising a mast cell degranulation-blocking agent and/or a mast cell activation-blocking agent (Abstract). Lindsberg teaches that a preferable mast cell degranulation-blocking agent is a histamine-1 receptor antagonist including hydroxyzine (paragraphs 0036-0037). Lindsberg further teaches other agents that inhibit mast cell secretion and proliferation including flavonoids such as quercetin optionally in combination with chondroitin sulfate (paragraph 0038).

A person of ordinary skill in the art would have been motivated to combine hydroxyzine, quercetin and chondroitin sulfate because Linsdberg teaches all of the agents to be used for the same purpose (i.e., art recognized equivalents). A practitioner would have reasonably expected a composition effective in blocking mast cell granulation.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... The idea of combining them flows logically from their

having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Therefore, in Lindsberg, it would have been prima facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to have combined hydroxyzine, quercetin and chondroitin sulfate in order to form a new composition effective in blocking mast cell granulation.

It is noted that claims 39-42 are composition claims and as such any intended use recitation such as "for treating the inflammatory components of pelvic endometriosis" in claim 39 does not alone show patentable distinction. A recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim.

Response to Arguments

Regarding the claim for priority, applicant submitted an amendment to the Specification stating,

> The present application is a CIP of copending PCT02/00476, filed 01/03/2002, which is a CIP of copending USSN 09/771,669, filed 01/30/2001 (now USPN 6984667), which is a CIP of copending USSN 09/056707, filed 04/08/1998 (now USPN 6689748).

See page 2 of Remarks. The examiner acknowledges the claim for priority, however it is objected to because the statement is contradicting the records of the PTO. Applicant's Oath filed 3/30/2004 states, "This application takes priority under 35 USC

120 from US serial Nos. 09/056,707, filed 4/8/1998 and 09/771,669, filed 1/30/2001 and under 35 USC 119 from PCT/US02/00476, filed 01/03/2002". Applicant's Bib Data Sheet and Continuity/Foreign Data Report contain no recitations of priority. The Continuity/Foreign Data report (see attached) for PCT/US02/00476 indicates that said PCT is a CON of 09/771669 and the instant application is a CON of said PCT and the Continuity/Foreign Data Report for 09/771,669 (see attached) does not indicate any reference to 09/056,707. Thus the examiner is unable to verify the priority claims applicant is making. Applicant is encouraged to review CFR § 1.78 for the proper practices of changing/correcting priority claims. CFR § 1.78 states, "A petition to accept an unintentionally delayed claim under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior filed application must be accompanied by: (i) The reference required by 35 U.S.C. 120 and paragraph (a)(2) of this section to the prior filed application, unless previously submitted; (ii) The surcharge set forth in § 1.17(t); and (iii) A statement that the entire delay between the date the claim was due under paragraph (a)(2)(ii) of this section and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional." Furthermore, applicant has not particularly pointed out where in the prior-filed references support can be found for the limitations in question, namely, "protecting pelvic tissues from the inflammatory components of endometriosis" and "hydroxyzine". For these reasons, the examiner is maintaining the date for priority as 3/30/2004 at this time.

It is noted that applicant did not address the claim objection of claim 39. Therefore, said claim objection is maintained.

The amendment to claim 39 renders the rejection of claims 39-44 under 35 USC 112, 1st paragraph (i.e., new matter) moot in part. In particular, applicant amended "protecting against" to "treating" which renders the rejection of claims 39-42 moot, however claims 43 and 44 still contain the limitation "protecting". Thus, the rejection of claims 43 and 44 under 35 USC 112, 1st paragraph are maintained.

The amendment to claim 42 has remedied the new matter issue for the particular range of the olive kernel extract. At paragraph [037] of the Specification there is explicit support for the range of "300-1,200 mg" of unrefined kernel extract. However, the other ranges claimed "10-3,000 mg of chondroitin sulfate, quercetin, myricetin or rutin" and "25-10 mg of hydroxyzine" still appear to be new matter. At paragraph [037] of the Specification it states, "The preferred concentration range of the proteoglycan, hexosamine sulfate and flavone components of the oral formulation are 10-3,000 mg per tablet or capsule". While applicant is claiming the same numerical range, the components to be included in the formulation differ. The Specification states that proteoglycan, hexosamine sulfate and flavone components are all required while the claim states chondroitin sulfate, quercetin, myricetin or rutin (all in the alternative) can be included. Additionally, applicant has not addressed the hydroxyzine range of "25-100 mg" and the examiner has not been able to locate the applicable disclosure to

support said range. Thus, for these reasons, the rejection of claim 42 under 35 USC 112, 1st paragraph (i.e., new matter) is maintained.

As indicated above, the "amendment" to claim 44 corrects the antecedent basis of the claim. Thus, the rejection of claim 44 under 35 USC 112, 2nd paragraph is rendered moot. Accordingly, the rejection has been withdrawn.

Applicant's arguments with respect to the rejection under 35 USC 103 have been fully considered but they are not persuasive. Applicant argues that the Lindsberg reference did not become prior art under 103(a) until its date of publication, not date of filing. Applicant further states Lindsberg was published on 9/21/2006 which is after the instant application's filing date of 3/30/2004 and thus, can not be utilized as prior art. In response, the examiner respectfully disagrees. The Lindsberg reference can be utilized under 103(a) because it qualifies as prior art under 102(e). The MPEP § 2163.02 states,

> **III. THE SUPREME COURT HAS AUTHORIZED 35 U.S.C. 103 REJECTIONS BASED ON 35 U.S.C. 102(e)**
>
> U.S. patents may be used as of their filing dates to show that the claimed subject matter is anticipated or obvious. Obviousness can be shown by combining other prior art with the U.S. patent reference in a 35 U.S.C. 103 rejection. *Hazeltine Research v. Brenner*, 382 U.S. 252, 147 USPQ 429 (1965). Similarly, certain U.S. application publications and certain international application publications may also be used as of their earliest effective U.S. filing dates (which will include certain international filing dates) to show that the claimed subject matter would have been anticipated or obvious.

Lindsberg has an effective filing date of 2/13/2003 which is prior to instant application's filing date of 3/30/2004. For these reasons, applicant's arguments are unpersuasive. Therefore, the rejection under 35 USC 103 is maintained.

NEW REJECTIONS

The following rejections are new in light of applicant's amendment submitted 12/26/2007:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 includes the limitation, "10-3,000 mg of chondroitin sulfate, quercetin, myricetin or rutin". Claim 42 depends from claim 39. Independent claim 39 includes the limitation "said composition comprising anti-inflammatory effective amounts of a non-bovine, heavily-sulfated proteoglycan, one or more flavonoids compounds and hydroxyzine". Claim 42 is essentially broadening the scope of claim 39 because it no longer requires a sulfated proteoglycan and one or more flavonoids. Thus, the claim is indefinite. Correction is respectfully requested.

Conclusion

All claims have been rejected; no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/

Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615